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REMARKS

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Claims 1-6, 8-14 and 16-17 are pending of the presented application. The Examiner has rejected Claims 1-6, 8-14 and 16-17. By the above amendments, new Claims 18-20 have been added. Support for new Claim 18 is found on page 30, line 18-page 31, line 3 (Example B14), and support for new Claims 19-20 is found on page 16, lines 23-25 of the specification as filed. After entry of the amendments, Claims 1-6, 8-14 and 16-20 will remain pending and under consideration.

The Examiner has rejected Claim 12 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Examiner has identified several points, which are addressed individually below.

- 1. The Examiner objects that the term "addition salt" in claims 1 and 6 is indefinite as it is not clear what is the structural make-up of the product of the "addition" process. Applicants direct the Examiner's attention to page 7, line 30 through page 8, line 23 which clearly describes what "addition salts" are and how they are made. Applicants urge that the term is not indefinite as asserted by the Examiner and that one of ordinary skill in the art would clearly understand the term. Applicants therefore respectfully request that the Examiner withdraw this rejection.
- 2. The Examiner has objected that the phrase "quartenary amine" in claims 1 and 6 is unclear. Applicants respectfully traverse. Applicants submit that the term "quartenary amine" is a well-known art term in Organic Chemistry to describe the situation when a nitrogen atom in an organic molecule is attached to four groups thereby having positive charge. Since the term "quartenary amine" would be clearly understood by one

of ordinary skill in the art, Applicants respectfully request that the Examiner withdraw this rejection.

- 3. The Examiner has objected that the use of parenthesis in various R groups of Claim 1 renders the claim unclear. Applicants respectfully traverse. Applicants submit that the term "di(methyl)aminocarbonyl" would be clearly understood by one of ordinary skill in the art and that the parenthesis do not render it indefinite. Since the metes and bounds of Claim 1 are readily defined such that a potential infringer could readily determine whether conduct was within or outside the scope of the claim, Applicants maintain that Claim 1 meets the requirements of §112, second paragraph.
- 4. The Examiner objects that the recitation in Claims 1 and 8 that R^4 and R^5 can be taken together to form a "azido" is indefinite as it is not clear how such a group could be formed. The term "azido" is a well-known art term in Organic Chemistry to describe an "-N₃" moiety. Thus, Applicants submit that one of ordinary skill in the art would readily understand how the moiety "NR⁴R⁵" can form an azido group. Applicants therefore respectfully request that the Examiner withdraw this rejection.
- 5. Claims 14 and 16 have been objected to by the Examiner as being substantial duplicates. Applicants submit that Claim 16 has additional limitations which are not present in Claim 14 and is of narrower scope than Claim 14. Therefore, the claims are not substantial duplicates and Applicants request that the Examiner withdraw this rejection.

In view of the above amendments and comments, Applicants respectfully request that the Examiner withdraw the rejections of Claims 1, 2, 4-5 and 10 under §112, second paragraph.

The Examiner has rejected Claims 1-6, 8-14, and 16-17 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states, "There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same bioactivity profile since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same." Applicants respectfully traverse this rejection.

Applicants submit that the specification adequately teaches one of ordinary skill in the art how to make and use the claimed compounds to treat HIV infection. With respect to the adequacy of disclosure that a claimed genus possess an asserted utility, the disclosure of representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art that the claimed genus would possess the asserted utility. The specification clearly discloses use of the instant compounds for treating HIV infection (see e.g., page 16, line 8 to page 17, line 6). Moreover, page 17, line 8 to page 21, line 30 of the specification teaches how the compounds are used (e.g., route of administration, dosages) to treat HIV infection. Applicants urge that the instant specification provides a teaching of how to use the invention which would be credible to the skilled artisan, and moreover, that one of ordinary skill in the art would be able to use the compounds for the stated utility without undue experimentation.

Moreover, an Applicant's assertion of utility creates a presumption of utility and the Examiner has the initial burden of challenging a presumptively correct assertion of utility in the disclosure; only after the Examiner provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince

such a person of the invention's asserted utility. Applicants maintain that the Examiner has not provided evidence that would cause the skilled artisan to doubt Applicants' teachings of utility which are set forth in detail above. Therefore, Applicants maintain that the Examiner has failed to establish a prima facie case that the claimed invention lacks utility.

In view of the above comments, Applicants maintain that the entire scope of the invention is adequately enabled and Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6, 8-14, and 16-17 based on §112, first paragraph.

The Examiner has rejected Claims 1-6 and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Hutchings et al. US 6,048,866. The Examiner states:

Instant claims differs from the reference in requiring R^{2a} to be in the para position of aminophenyl ring. However, Hutchings et al. teaches both the equivalency and interchangeability of herein exemplified substituents with that claimed herein. . . Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in pyrimidine ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the used taught by the art in view of the equivalency teaching outline above.

Applicants respectfully traverse this rejection.

Although Hutchings et al. teach substituted anilinopyrimidines, <u>none</u> of the 31 exemplified compounds contain a para-substituted cyano or aminocarbonyl (Applicants' R^{2a} moiety) phenyl group attached to the aminopyrimidine group, as is required by the instant claims. Applicants maintain that the

teaching of Hutchings et al. would not motivate one of ordinary skill in the art to make the claimed compounds wherein the R^{2a} moiety is in the para position and is a cyano or aminocarbonyl derivative containing group. Thus, Applicants submit that the teaching of Hutchings et al does not render the present invention obvious and Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6 and 11-13 under $\S 103$ (a).

The Examiner has rejected Claims 1-6 and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Davis et al. US 6,093,716.

Davis et al. teach pyrimidineamines substituted with a heterocyclic group. By contrast, the instant claims are drawn to pyrimidineamines substituted with a para-substituted phenyl group wherein the phenyl substituent is a cyano or aminocarbonyl derivative containing moiety. Thus, the compounds disclosed by Davis et al. are structurally remote from the claimed compounds. Applicants urge that the teaching of Davis et al. would not motivate one of ordinary skill in the art to make the claimed compounds wherein the pyrimidineamine is substituted with a para-substituted phenyl group wherein the phenyl substituent is a cyano or aminocarbonyl derivative containing moiety. Thus, Applicants submit that the teaching of Davis et al does not render the present invention obvious and Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6 and 11-13 under §103(a).

The Examiner has rejected Claims 1-6 and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Buckman et al. US 5,691,364. Applicants respectfully traverse this rejection. The Examiner states:

Buckman et al. teach several 2,4-disubstituted pyrimidnes which includes compounds generically embraced herein for the treatment of thrombosis and related disorders. . . .

Instant claims differs from the reference in requiring R^{2a} to be in the para position of the aminophenyl ring.

However, Buckman et al. teaches both the equivalency and interchangeability of herein exemplified substituents with that claimed herein. . . . Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in pyrimidine ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the used taught by the art in view of the equivalency teaching outline above.

Applicants respectfully traverse this rejection.

Although Buckman et al. disclose more than 400 specific compounds, only two of the exemplified compounds are drawn to a pyrimidine compounds. The overwhelming majority of compounds taught by Buckman et al. are pyridinyl derivatives rather than pyrimidine. Moreover, the two pyrimidine compounds disclosed by Buckman et al are linked to the phenyl substituent via an oxygen linker rather than a nitrogen linker as is required by the pyrimidineamine compounds of the instant invention. Additionally, the claims of Buckman et al. do not cover pyrimidine derivatives, but only pyridinyl derivatives. Clearly, the teaching of Buckman et al. would not motivate one of ordinary skill in the art to make the pyrimidineamine compounds claimed in the instant application. Thus, Applicants urge that the teaching of Buckman et al does not render the present invention obvious and Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6 and 11-13 under §103(a).

In view of the above amendments and comments, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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